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MEMORANDUM

Subject: Management of Risks Associated with Lead and Arsenic in Residential Soils,
Vasquez Boulevard/Interstate 70 Superfund Site

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To: Administrative Record File

The purpose of this memorandum is to provide the basis for EPA's determination that remedial action is necessary to address unacceptable human health risks associated with potential exposure to lead and arsenic in the residential soils Operable Unit 1 of the Vasquez Boulevard/Interstate 70 (VB/I70) Superfund Site. This memorandum also provides the basis for VB/I70 Site-specific preliminary action levels for lead and arsenic in residential soil.

Human Health Risks Associated with Potential Exposure to Arsenic

EPA completed a quantitative baseline human health risk assessment (EPA, 2001a) which evaluated current and anticipated future exposure of residents within VB/I70 Site Operable Unit 1 to concentrations of arsenic measured in soil collected from their yards. The reasonably anticipated future land use of the residential area of VB/I70 is residential. It is not expected that the current land use will change. The exposure pathways of concern to residents are incidental ingestion of soil and dust, ingestion of home grown garden vegetables, and intentional ingestion of large amounts of soil by children with soil pica behavior. The adverse health effects associated with arsenic exposure that were considered by EPA are:

- Acute non-cancer effects (irritation of the gastrointestinal tract leading to nausea and vomiting). EPA evaluated the risk that such effects could potentially result from a one-time exposure to arsenic by a child with soil pica behavior who happens to ingest soil from a small area of a yard that contains arsenic levels higher than the average concentration in the yard.



- Subchronic non-cancer effects (diarrhea, vomiting, anemia, injury to blood vessels, damage to kidney and liver, and impaired nerve function). EPA evaluated the risk that such effects could potentially result from lower level exposure for periods of a few months to several years by a child who plays preferentially in a small area of a yard during the summer months and happens to incidentally ingest soil at a rate characteristic of the upper percentile of the general population.
- Chronic non-cancer effects (similar to subchronic effects but also include skin abnormalities). EPA evaluated the risk that such effects could potentially result from lower level exposure over a long period of time such as that associated with long term incidental ingestion of soil and dust and ingestion of home grown garden vegetables by long time area residents who have spent their childhood and adult years living at the same residence.
- Chronic cancer effects (skin cancer, internal cancer including cancer of the bladder and lung). EPA evaluated the risk that such effects could potentially result from lower level exposure over a long period of time such as that associated with long term incidental ingestion of soil and dust and ingestion of home grown garden vegetables by long time area residents who have spent their childhood and adult years living at the same residence.

The baseline human health risk assessment quantified potential risks to residents with average levels of exposure and to residents with "reasonable maximum" levels of exposure. The intent of the reasonable maximum exposure scenario is to estimate an exposure case that is conservative, yet still within the range of possible exposures. Reasonable maximum is generally intended to characterize the 90th-95th percentile of the exposed population. Consideration of both average exposures and reasonable maximum exposures gives the risk manager a range of risk estimates to provide an indication of the variability, uncertainty, and inherent protectiveness in the assumptions used to quantify potential risks. Average exposures are sometimes referred to as "central tendency exposures". In this memorandum, the "average" and "central tendency" are used interchangeably.

Risk of Acute Effects

EPA's evaluation of the risk of acute effects from exposures to arsenic associated with soil pica behavior in children is considered to be a screening level evaluation because of the substantial uncertainty which exists in most of the exposure assumptions. The screening level calculations performed for the VB/I70 Site indicate:

- **Average soil pica exposures** may result in doses of arsenic that range from less than or equal to the reference dose (hazard quotient ≤ 1) to 100 times the reference dose (hazard quotient = 100). Between 294 and 1511 properties have arsenic concentrations that are

predicted to result in an acute hazard quotient greater than 1 for average soil pica exposures.

- **Reasonable maximum soil pica exposures** may result in doses of arsenic that range from less than or equal to the reference dose (hazard quotient ≤ 1) to 300 times the reference dose (hazard quotient = 300). Between 662 and 1841 properties have arsenic concentrations that are predicted to result in an acute hazard quotient greater than 1 for reasonable maximum soil pica exposures.

Risk of Subchronic Non-Cancer Effects

The baseline human health risk assessment indicates:

- At any residential property in VB/I70, children with **average levels of exposure** may incidentally ingest soil with arsenic and the resulting dose is predicted to be less than or equal to the subchronic reference dose (hazard quotient ≤ 1). There are no properties with arsenic concentrations that are predicted to result in a subchronic hazard quotient greater than 1 for average levels of exposure.
- Area children with **reasonable maximum levels of exposure** may incidentally ingest soil with arsenic that results in a dose ranging from less than or equal to the subchronic reference dose (hazard quotient ≤ 1) to 3 times the subchronic reference dose (hazard quotient = 3). There are 7 properties with arsenic concentrations that are predicted to result in a subchronic hazard quotient greater than 1 for reasonable maximum levels of exposure.

Risk of Chronic Non-Cancer Effects

The baseline human health risk assessment indicates:

- Area residents with **average levels of exposure** may, over a long period of time, incidentally ingest soil with arsenic and ingest garden vegetables with arsenic that results in a dose ranging from less than or equal to the chronic reference dose (hazard quotient ≤ 1) to 2 times the chronic reference dose (hazard quotient = 2). There are only 2 properties with arsenic concentrations that are predicted to result in a chronic hazard quotient greater than 1 for average levels of exposure.
- Area residents with **reasonable maximum levels of exposure** may, over a long period of time, incidentally ingest soil with arsenic and ingest garden vegetables with arsenic that results in a dose ranging from less than or equal to the chronic reference dose (hazard quotient ≤ 1) to 5 times the chronic reference dose (hazard quotient = 5). There are 26 properties with arsenic concentrations that are predicted to result in a chronic hazard quotient greater than 1 for reasonable maximum levels of exposure.

Cancer Risks

The baseline human health risk assessment indicates:

- Area residents with **average levels of exposure** may, over a long period of time, incidentally ingest soil with arsenic and ingest garden vegetables with arsenic that results in a cancer risk ranging from 2×10^{-6} to 9×10^{-5} . There are no properties where cancer risks are predicted to exceed 1×10^{-4} for average levels of exposure.
- Area residents with **reasonable maximum levels of exposure** may, over a long period of time, incidentally ingest soil with arsenic and ingest garden vegetables with arsenic that results in a cancer risk ranging from 1×10^{-5} to 8×10^{-4} . There are 99 properties where cancer risks are predicted to exceed 1×10^{-4} for reasonable maximum levels of exposure.

Table 1 summarizes the results of the baseline human health risk assessment.

Determination of Unacceptable Risks due to Arsenic Exposure

EPA guidance contained in the Office of Solid Waste and Emergency Response (OSWER) Directive 9355.0-30 (EPA, 1991) states that where the cumulative carcinogenic site risk to an individual based on the reasonable maximum exposure (RME) for both current and future land use is less than 10^{-4} , and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted. The guidance further states that EPA should clearly explain why remedial action is warranted if baseline risks are within the acceptable risk range of 10^{-6} to 10^{-4} . A risk manager may decide that a level of risk lower than 10^{-4} warrants remedial action where, for example, there are uncertainties in the risk assessment results.

Risks will be managed by applying EPA guidance in OSWER Directive 9355.0-30 to each individual residential yard in Operable Unit 1 of the VB/I-70 Site. This is because the exposure unit in the baseline human health risk assessment is the individual residential yard (or a sublocation of the yard) and baseline risks were calculated for each individual residential yard. EPA will make decisions about whether remedial action is necessary on a yard by yard basis.

Consistency with the EPA guidance in OSWER Directive 9355.0-30 is thus achieved at the VB/I70 Site by comparing the predicted carcinogenic and non-carcinogenic risks at each individual property to the guidelines described in the directive.

Table 1 reveals that there are between 662 and 1841 individual properties where the predicted RME hazard quotient exceeds 1 for potential acute effects associated with soil pica behavior. In accordance with EPA guidance, remedial action is warranted at these properties.

Table 1 also reveals that there are 99 individual properties where predicted RME cancer risks exceed 10^{-4} . In accordance with EPA guidance, remedial action is warranted at these 99 properties. Of these 99 properties, there are 26 properties where the predicted RME hazard quotient exceeds 1 for chronic non-cancer effects, and 7 properties where the predicted RME hazard quotient exceeds 1 for both subchronic and chronic non-cancer effects.

Remedial action at the 99 properties which addresses unacceptable predicted RME cancer risks will also address unacceptable predicted RME non-cancer risks of subchronic and chronic effects but will NOT address unacceptable RME risks of acute effects.

Consideration of Uncertainties in the Baseline Human Health Risk Assessment for Arsenic

Uncertainties in the Estimates of Cancer Risk

OSWER Directive 9355.0-30 states that consideration of uncertainties in the baseline risk assessment may lead a risk manager to decide that risks lower than 10^{-4} are unacceptable, triggering the need for remedial action. EPA considered the uncertainty in the arsenic risk calculations for VB/I70 to determine whether remedial action is needed at properties where risks are predicted to be less than or equal to 10^{-4} .

EPA undertook several studies to increase the accuracy (reduce uncertainty) of the risk estimates for the VB/I70 Site. The first was a study to investigate the relative bioavailability of arsenic in the soil found in the VB/I70 Site (EPA, 2001c). In the absence of site specific information on relative bioavailability, it is common practice to use a default assumption as the value for this parameter or to ignore relative bioavailability altogether in risk estimates. Measurements based on site specific soils significantly reduce the uncertainty in estimates of this parameter. In the study on VB/I70 Site soils, relative bioavailability was measured in five different soils collected from residential yards in the Site. Variability in the relative bioavailability of arsenic was observed between the five different site soils. EPA used a conservative estimate of the mean of the five values in the baseline risk assessment. This approach is expected to overestimate the true value of this parameter for any given soil in the residential yards in the Site. Thus the accuracy of the risk estimate was increased by using a VB/I70 Site-specific value and protectiveness was achieved by using a conservative estimate of the mean of all values measured at the Site.

The second study (EPA, 2001b) was an investigation into the VB/I70 Site-specific relationships between:

- arsenic in yard soil and arsenic in house dust;
- arsenic in yard soil and arsenic in garden soils;
- arsenic in garden soils and arsenic in garden vegetables.

Establishing these Site-specific relationships reduces the uncertainty in quantifying exposure and risk associated with incidental ingestion of soil and dust and ingestion of garden vegetables.

When risks are described as point estimates, it is difficult to evaluate the level of protectiveness inherent in the exposure assumptions used to calculate the risks. A point estimate of risk also does not provide any information about the uncertainties in the risk assessment. Uncertainty can be analyzed to some degree by comparing the central tendency point estimates and the RME point estimates. Large differences between the RME risk estimate and the central tendency risk estimate may indicate either a large amount of uncertainty in the estimates or a large amount of variability in the exposure parameters within the exposed population. At the VB/I70 site, the risk estimates indicate that cancer risks are within an acceptable range at properties if average or central tendency exposures are considered. Cancer risks are unacceptable at 99 properties if RME exposures are considered.

Another way to analyze uncertainty in risk estimates is by using Monte Carlo modeling, a computer based mathematical technique in which exposure parameters are characterized as probability density functions (PDF) rather than as point estimates. The premise of Monte Carlo modeling is that every assumption about exposure (e.g., the frequency of contact, soil ingestion rate) is a variable and can be modeled as a PDF. The PDF reflects a range of values with associated probabilities. In a Monte Carlo analysis, a risk calculation is repeated thousands of times using statistical techniques to select exposure values from the PDFs that characterize them. The thousands of combinations of exposure assumptions results in a range of risk estimates expressed as a distribution of risks that may exist at the site for the population being considered.

In theory, a Monte Carlo analysis can be performed for every property within the VB/I70 site. To simplify the analysis, EPA performed screening level Monte Carlo modeling of exposure and risk associated with a selected concentration of arsenic in soil at the VB/I70 Site. The results, which are included in the final Human Health Baseline Risk Assessment, indicate that the point estimate of risk for the RME scenario is located at the 99th percentile of the risk distribution. This means that it is highly unlikely that the chronic arsenic exposures EPA has characterized for the VB/I70 site are actually occurring in the people who reside there. The 99th percentile indicates that there is only a 1% chance that the RME chronic exposure is actually occurring at the Site and that only 1% of the population experience the RME exposure. These results indicate that the combination of exposure assumptions used by EPA for the chronic arsenic exposure assessment at this site may be at the upper bound of or even beyond the reasonable maximum exposure scenario.

The Monte Carlo analysis also showed that at properties where point estimate of risk is 1×10^{-4} , risks in the 90th percentile - 95th percentile range (the RME range) are 2×10^{-5} to 7×10^{-5} .

The uncertainty analysis indicates that actual risks are much more likely to be lower than the calculated point estimates of risks. Providing protection at the 1×10^{-4} risk level based on the point estimates of risk is likely to provide a level of protectiveness for the RME scenario in the range of 2×10^{-5} to 7×10^{-5} . Therefore, in accordance with EPA guidance in OSWER Directive 9355.0-30, based on EPA's consideration of the uncertainties in the cancer risk assessment for arsenic, remedial action is not warranted at those properties in VB/I70 where the point estimates of risk are less than or equal to 10^{-4} .

Uncertainties in the Estimates of Acute Risks

EPA also considered the uncertainty in the calculation of the risk of acute effects from exposures to arsenic associated with soil pica behavior in children. Two important facts were considered: (1) the distribution of soil ingestion rates for children with soil pica behavior is not known and (2) the frequency with which such children exhibit the behavior is also not known. Therefore, the application of Monte Carlo techniques to analyze the uncertainty in the calculations of acute risk is difficult and was not performed by EPA for the VB/I70 Site.

However, EPA characterized the theoretical average and RME point estimates of acute risk in screening level calculations. These estimates suggest that there are between 294 and 1511 individual properties with soil arsenic concentrations that are predicted to result in acute hazard quotient greater than 1 for the average soil pica scenario. There are between 662 and 1841 individual properties with soil arsenic concentrations that are predicted to result in acute hazard quotient greater than 1 for the RME soil pica scenario. The wide range of potentially affected properties, 294-1841, reflects the substantial uncertainty in quantifying these risks.

EPA guidance contained in OSWER Directive 9355.0-30 states that where the non-carcinogenic hazard quotient for an individual based on the reasonable maximum exposure for both current and future land use is less than 1, action generally is not warranted. EPA considered the range of 662 -1841 properties where application of this guidance indicates remedial action is warranted. This range is referred to as Case 1 (1841 properties) and Case 2 (662 properties) in the Baseline Human Health Risk Assessment. EPA also considered the following:

- EPA is not aware of any reported cases of acute arsenic toxicity attributable to ingestion of arsenic in soil.
- Limited data on urinary arsenic levels in residents of the VB/I70 area and the nearby Globeville neighborhood do not reveal the occurrence of high soil intakes by children.
- Inquiries by the Colorado Department of Public Health and Environment (CDPHE) into reports of known or suspected cases of arsenic poisoning in the community surrounding the VB/I70 site resulted in their conclusion, stated in a July 25, 2001 letter, that "...it appears that there is no obvious or identifiable

problem of arsenic exposure from environmental sources in the area of concern.” (CDPHE, 2001).

These considerations suggest that arsenic risk from soil pica behavior may not be as significant as the theoretical calculations suggest. However, because of the high uncertainty regarding the magnitude and frequency of soil pica behavior, more reliable risk estimates for this scenario will not be possible until better data are collected on soil intake rates characteristic of soil pica behavior along with direct measurements of soil related exposures to arsenic.

Because of the substantial uncertainty in the risk calculations, the lack of evidence of soil pica behavior, the further lack of evidence that such behavior actually results in exposure to arsenic, and the lack of obvious or identifiable problem of arsenic exposure in VB/I70, EPA has determined that remediation is warranted at the minimum number of properties, 662, to address the risk of acute effects from theoretical exposures to arsenic associated with soil pica behavior in children who reside in the VB/I70 site. The Case 2 soil pica exposure scenario is considered the more appropriate scenario on which to base risk management decisions for risks associated with soil pica behavior. Remedial action is warranted at properties where the acute hazard quotient exceeds 1 for the Case 2 exposure scenario.

Development of Preliminary Action Levels for Arsenic in Residential Soils at VB/I70

Preliminary action levels are exposure point concentrations (EPCs) above which some remedial action is warranted. At the VB/I70 Site Operable Unit 1, the arsenic EPC is a conservative estimate of the mean concentration within an individual yard. An EPC for arsenic was calculated for each individual yard as part of the Baseline Human Health Baseline Risk Assessment. Properties where remedial action is warranted will be identified by comparing the EPCs to the preliminary action levels. Consistent with OSWER Directive 9355.0-30, preliminary action levels for arsenic in residential soils at VB/I70 are:

- An EPC of 47 milligrams per Kilogram (mg/Kg) which is the level of arsenic in soil associated with an acute hazard quotient which exceeds 1 for the Case 2 RME soil pica scenario.
- An EPC of 240 mg/Kg which is the level of arsenic in soil associated with an RME cancer risk which exceeds 1×10^{-4} as a point estimate, 2×10^{-5} as the 90th percentile of the risk distribution, and 7×10^{-5} as the 95th percentile of the risk distribution.

Human Health Risks Associated with Potential Exposure to Lead

EPA's quantitative baseline human health risk assessment for the VB/I70 Site Operable Unit 1 also considered the health risks associated with exposure of residents to concentrations of lead measured in soil collected from their yards. The population of most

concern for exposure to lead in soil is young children. EPA evaluates risks associated with exposure to lead by considering total exposure via all sources and pathways in the environment rather than to site related exposures only. This requires assumptions about the level of lead in food, air, water, and paint as well as the level of lead measured in yard soils.

The adverse health effect associated with lead exposure that was considered by EPA is lead-induced neurobehavioral effects in children. EPA's OSWER determined that, in Superfund Site cleanups, EPA will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% of exceeding a blood lead level of 10 micrograms per deciliter (ug/dL) (EPA 1994). EPA has identified this blood lead level as the level at which health effects which warrant avoidance in children begin to occur.

The baseline human health risk assessment indicates that there is a greater than 5% chance that a child will have a blood level of 10 ug/dL as a result of exposure to lead in soil at 1331 properties. This prediction of lead risk was determined by using EPA's Integrated Exposure/Uptake Biokinetic (IEUBK) Model. In order to increase the accuracy of the model results, EPA used VB/I70 Site-specific data on the relationship between lead in the fine and bulk fractions of soil, the relationship between lead in yard soil and lead in house dust (EPA, 2001b), and the relative bioavailability of lead in soils (EPA, 2001d).

Consideration of Uncertainties in the Baseline Human Health Risk Assessment for Lead

In order to investigate some of the sources of uncertainty in the IEUBK model predictions for the VB/I70 Site, EPA ran the model a number of times, varying the values for dietary lead intake, geometric standard deviation of blood lead levels, and soil intake rate to reflect recently published data. The results of the alternative model runs are presented in the final Baseline Human Health Risk Assessment document.

The range of results indicate that there is a greater than 5% chance that a child will have a blood level of 10 ug/dL as a result of exposure to lead in soil at between 2 and 1331 properties. This wide range indicates substantial uncertainty in predictions of blood lead levels using the IEUBK model at the VB/I70 site.

EPA also predicted blood lead levels in children in VB/I70 using a different model than the IEUBK. The results of this modeling effort, also presented in the final Baseline Human Health Risk Assessment, indicate that there are no properties where lead levels in soil are predicted to result in a greater than 5% chance that a child will have a blood level of 10 ug/dL, suggesting that remedial action to address lead in soil may not be warranted.

Consideration of Observed Blood Lead Values in Children Who Reside in VB/I70

EPA reviewed the available information on measured blood lead levels in the population of children in VB/I70 to better understand how well the IEUBK model was predicting blood lead levels at the Site. The CDPHE offered three separate blood lead testing programs to children living in the VB/I70 site during the period 1995 through 2000 and provided the results of this testing to EPA. Although the blood lead testing was not designed or intended to support risk assessment, the data support the following conclusions:

- elevated blood lead levels do occur in children residing within the site
- soil is not likely to be the main source of elevated blood lead levels in children
- the elevated blood lead levels that were observed in children within VB/I70 are not clearly different from the elevated levels observed in children who live outside of VB/I70

Development of Preliminary Action Levels for Lead in Residential Soils at VB/I70

Each alternative IEUBK model run predicts that EPA's health goal for lead in soil will be met at a specific average soil lead concentration or lead EPC in an individual yard. The alternative model runs performed by EPA resulted in a range of such EPCs. These are average lead concentrations in a yard above which remedial action may be warranted to achieve EPA's health goal and are referred to as preliminary action levels. The range of soil lead concentrations is presented in Table 2.

EPA considered the following factors in developing the preliminary action levels for lead from the range provided in Table 2 that will be used in the feasibility study for the VB/I70 Site:

- Available blood lead data indicates that soil is not likely to be the main source of elevated blood lead levels in children in VB/I70.
- Predictions using an alternative model suggest that remedial action of soil may not be required to achieve EPA's health goal for lead in soil.

These factors led EPA to develop two preliminary action levels for lead in soil at VB/I70:

(1) 208 mg/Kg as the yard EPC. This is the soil concentration at the lowest end of the range of soil concentrations that the IEUBK model predicts EPA's health goal will be exceeded; and

References:

CDPHE. 2001. Letter from Michael Wilson, Ph.D., Section Chief, Environmental Toxicology, to Jeffrey Lybarger, M.D., M.S., Director, Division of Health Studies, Agency for Toxic Substances and Disease Registry Re: "Arsenic Poisoning Inquiry" dated July 25, 2001.

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EPA. 2001b. Remedial Investigation Report Vasquez Boulevard/I-70 Site Operable Unit 1. Prepared by Washington Group International for the EPA.

EPA, 2001c. Relative Bioavailability of Arsenic in Soils from the VBI70 Site. Report prepared for EPA Region VIII by Syracuse Research Corporation. January 2001.

EPA, 2001d. Relative Bioavailability of Lead in Soils from the VBI70 Site. Report prepared for EPA Region VIII by Syracuse Research Corporation. February 2001.

Table 1 Summary of Baseline Human Health Risk Assessment for Arsenic VB/I-70 Residential Soils				
Health Effect	Average or Central Tendency Exposure		Reasonable Maximum Exposure	
	Range of Calculated Risks	# properties where risks are predicted to be unacceptable	Range of Calculated Risks	# properties where risks are predicted to be unacceptable
acute non-cancer effects	$.07 \leq HQ^1 \leq 100$	294-1511	$0.2 \leq HQ \leq 300$	662- 1841
subchronic non-cancer effects	$.003 \leq HQ \leq 0.8$	0	$0.01 \leq HQ \leq 3$	7
chronic non-cancer effects	$.04 \leq HQ \leq 2$	2	$0.1 \leq HQ \leq 5$	26
cancer effects	$2 \times 10^{-6} \leq \text{Cancer Risk} \leq 9 \times 10^{-5}$	0	$1 \times 10^{-5} \leq \text{Cancer Risk} \leq 8 \times 10^{-4}$	99

1. HQ = hazard quotient, defined as ratio of predicted site dose to reference dose

Table 2 Alternative Preliminary Action Levels for Lead in Soil VB/I70 Site			
IEUBK Model Run	Dietary Lead Intake Values	Geometric Standard Deviation of Blood Lead Values	Predicted Lead Soil Level at P10 < 5%¹ (mg/Kg)
1	default	1.6 (default)	208
2	revised	1.6 (default)	246
3	default	1.4	326
4	revised	1.4	362
5	revised	1.3	443
6	default	1.2	542
7	revised	1.2	581

1. P10 < 5% = less than 5% probability that blood lead levels exceed 10 ug/dL